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Attorneys for Defendant and Counterclaim Plaintiff Sawai Pharmaceutical Co., Ltd.

UNITED STATES DISTRICT COURT
SOUTHERN DISTRICT OF NEW YORK

Kowa Company, Ltd., Kowa Pharmaceuticals America, Inc., and Nissan Chemical Industries, Ltd. Plaintiffs, v. Sawai USA, Inc. and Sawai Pharmaceutical Co., Ltd. Defendants.	Civil Action No. 1:14-CV-5575 (PAC) **ANSWER AND COUNTERCLAIMS OF DEFENDANT SAWAI PHARMACEUTICAL CO., LTD.**

Defendant Sawai Pharmaceutical Co., Ltd. ("Sawai Pharma") by and through its undersigned attorneys, hereby submits its Answers, Defenses, and Counterclaims to Plaintiffs'

Kowa Company, Ltd., Kowa Pharmaceuticals America, Inc. (collectively "Kowa") and Nissan Chemical Industries, Ltd. ("NCI") (together collectively "Plaintiffs") Complaint. Except as specifically admitted herein, Sawai Pharma denies the allegations contained in the Complaint by Plaintiffs and maintains that Plaintiffs are not entitled to any relief.

JURISDICTION AND VENUE

1. Paragraph 1 contains conclusions of law to which no response is required. To the extent an answer is required, Sawai Pharma admits that this is an action by Plaintiffs against Sawai USA, Inc. ("Sawai USA") and Sawai Pharma alleging patent infringement. Sawai Pharma admits that this Court has subject matter jurisdiction pursuant to 28 U.S.C. § 1338(a). Sawai Pharma will not contest personal jurisdiction or venue for purposes of this action only. Sawai Pharma denies the remaining allegations of Paragraph 1.

PARTIES

2. Upon information and belief, Sawai Pharma admits that plaintiff Kowa Company, Ltd. is a Japanese corporation having its principal place of business in Aichi, Japan and that plaintiff Kowa Pharmaceuticals America, Inc. is a Delaware corporation having its principal place of business in Montgomery, Alabama, and Sawai Pharma is without knowledge or information sufficient to form a belief as to the truth of the remaining allegations in Paragraph 2, and therefore denies the same.

3. Upon information and belief, Sawai Pharma admits that Nissan Chemical Industries, Ltd. is a Japanese corporation having its principal place of business in Tokyo, Japan, and Sawai Pharma is without knowledge or information sufficient to form a belief as to the truth of the remaining allegations in Paragraph 3, and therefore denies the same.

4. Sawai Pharma is without knowledge or information sufficient to form a belief as to the truth of the allegations in Paragraph 4, and therefore denies the same.

5. Sawai Pharma admits the allegation in paragraph 5.

6. Sawai Pharma admits that it is a corporation organized under the laws of Japan, with a principal place of business in Osaka, Japan. Sawai Pharma further admits that Sawai USA submitted an Abbreviated New Drug Application ("ANDA") No. 205955 to the U.S. Food and Drug Administration ("FDA") seeking approval for Pitavastatin Calcium Oral Tablets, 1 mg, 2 mg, and 4 mg. Sawai Pharma denies all remaining allegations in Paragraph 6.

7. Paragraph 7 contains legal conclusions to which no answer is required. To the extent an answer is required, Sawai Pharma denies the allegations in Paragraph 7.

8. Paragraph 8 contains legal conclusions to which no answer is required. To the extent an answer is required, Sawai Pharma denies the allegations in Paragraph 8.

The New Drug Application

9. Sawai Pharma avers that the electronic version of the FDA's publication, *Approved Drug Products with Therapeutic Equivalence Evaluations* (the "Orange Book"), identifies "KOWA CO" as the purported holder of New Drug Application ("NDA") No. 022363 for LIVALO® (Pitavastatin Calcium) Tablets, 1 mg, 2 mg and 4 mg. Sawai Pharma is without knowledge and information sufficient to form a belief as to the truth of the remaining allegations in Paragraph 9, and therefore denies the same.

10. Sawai Pharma avers that the Prescribing Information for LIVALO® provides, in relevant part, that LIVALO® is "indicated as an adjunctive therapy to diet to reduce elevated total cholesterol (TC), low-density lipoprotein cholesterol (LDL-C), apolipoprotein B (Apo B),

triglycerides (TG), and to increase HDL-C in adult patients with primary hyperlipidemia or mixed dyslipidemia." Sawai Pharma is without knowledge and information sufficient to form a belief as to the truth of the remaining allegations in Paragraph 10, and therefore denies the same.

11. Sawai Pharma avers that the Orange Book identifies August 3, 2009, as the approval date for LIVALO®. Sawai Pharma is without knowledge and information sufficient to form a belief as to the truth of the remaining allegations in Paragraph 11, and therefore denies the same.

12. Sawai Pharma is without knowledge or information sufficient to form a belief as to the truth of the allegations in Paragraph 12, and therefore denies the same.

THE PATENTS IN SUIT

13. Sawai Pharma admits that what purports to be a copy of U.S. Patent No. 5,856,336 ("the '336 patent") was attached to the Complaint as Exhibit A. Sawai Pharma further admits that the face of the '336 patent states that it issued on January 5, 1999, that it is entitled "Quinoline Type Mevalonolactones," and that Yoshihiro Fujikawa, Mikio Suzuki, Hiroshi Iwasaki, Mitsuaki Sakashita, and Masaki Kitahara are listed as inventors. Sawai Pharma further avers that the electronic records of the USPTO identify "Nissan Chemical Industries Ltd." as the purported assignee to the '336 patent. Sawai Pharma denies all remaining allegations in Paragraph 13.

14. Sawai Pharma is without knowledge or information sufficient to form a belief as to the truth of the allegations in Paragraph 14, and therefore denies the same.

15. Sawai Pharma admits that what purports to be a copy of U.S. Patent No. 6,465,477 ("the '477 patent") was attached to the Complaint as Exhibit B. Sawai Pharma further

admits that the face of the '477 patent states that it issued on October 15, 2002, that it is entitled "Stable Pharmaceutical Composition," and that Toyojiro Muramatsu, Katsumi Mashita, Yasuo Shinoda, Hironori Sassa, Hiroyuki Kawashima, Yoshio Tanizawa and Hideatsu Takeuchi are listed as inventors. Sawai Pharma further avers that the electronic records of the USPTO identify "Kowa Company, Ltd." and "Nissan Chemical Industries Ltd." as the purported assignees to the '477 patent. Sawai Pharma denies all remaining allegations in Paragraph 15.

16. Sawai Pharma is without knowledge or information sufficient to form a belief as to the truth of the allegations in Paragraph 16, and therefore denies the same.

17. Sawai Pharma admits that what purports to be a copy of U.S. Patent No. 8,557,993 ("the '993 patent") was attached to the Complaint as Exhibit C. Sawai Pharma further admits that the face of the '993 patent states that it issued on October 15, 2013, that it is entitled "Crystalline Forms of Pitavastatin Calcium," and that Paul Adriaan Van Der Schaaf, Fritz Blatter, Martin Szelagiewicz, and Kai-Uwe Schoening are listed as inventors. Sawai Pharma further avers that the electronic records of the USPTO identify "Nissan Chemical Industries Ltd." as the purported assignee to the '993 Patent. Sawai Pharma denies all remaining allegations in Paragraph 17.

18. Sawai Pharma is without knowledge or information sufficient to form a belief as to the truth of the allegations in Paragraph 18, and therefore denies the same.

19. Paragraph 19 contains legal conclusions to which no answer is required. To the extent an answer is required, Sawai Pharma avers that the FDA's Orange Book identifies NDA No. 022363 in connection with LIVALO® (Pitavastatin Calcium) Tablets 1 mg, 2 mg and 4 mg.

Sawai Pharma lacks knowledge and information sufficient to form a belief as to the truth of the remaining allegations in Paragraph 19, and therefore denies all such allegations.

20. Sawai Pharma is without knowledge or information sufficient to form a belief as to the truth of the allegations in Paragraph 20, and therefore denies the same.

21. Sawai Pharma denies the allegations in Paragraph 21.

COUNT I
(INFRINGEMENT OF THE '336 PATENT UNDER 35 U.S.C. §271(e)(2)(A)

22. Sawai Pharma restates and incorporates by references its answers to the allegations in Paragraphs 1-21.

23. Sawai Pharma admits that Sawai USA filed ANDA No. 205955 with the FDA seeking approval for Pitavastatin Calcium Tablets, 1 mg, 2 mg and 4 mg. Sawai Pharma denies all remaining allegations in Paragraph 23.

24. Paragraph 24 contains legal conclusions to which no answer is required. To the extent an answer is required, Sawai Pharma admits that Sawai USA's ANDA No. 205955 contains the bioavailability and/or bioequivalence data and/or bioequivalence waiver required by FDA. Sawai Pharma denies all remaining allegations in Paragraph 24.

25. Sawai Pharma admits that Sawai USA filed ANDA No. 205955 with the FDA seeking approval for Pitavastatin Calcium Tablets, 1 mg, 2 mg and 4 mg prior to the expiration of, among others, the '336 patent. Sawai Pharma denies all remaining allegations in Paragraph 25.

26. Sawai Pharma admits that Sawai USA sent a letter dated June 6, 2014, to Kowa Pharmaceuticals America, Inc., Kowa Company, Ltd. and Nissan Chemical Industries, Ltd. with notification that Sawai USA filed an ANDA with the FDA for approval of Pitavastatin Calcium

Tablets, 1 mg, 2 mg, and 4 mg. Sawai Pharma further admits that ANDA No. 205955 included a certification pursuant to 21 U.S.C. § 355(j)(2)(A)(vii)(IV). Sawai Pharma is without knowledge or information sufficient to form a belief as to the remaining allegations of paragraph 26, and therefore denies the same.

27. Sawai Pharma admits that the letter dated June 6, 2014 referenced in paragraph 26 above states that the '336 patent is "invalid and/or the valid claims therein as not infringed, either literally or under the doctrine of equivalents, by the manufacture, use, sale, offer for sale, and/or importation of the drug or drug product for which the present ANDA has been submitted." Sawai Pharma denies the remaining allegations in paragraph 27.

28. Sawai Pharma denies the allegations in Paragraph 28.

29. Sawai Pharma denies the allegations in Paragraph 29.

30. Sawai Pharma avers that the proposed labeling for the ANDA product indicates that Sawai USA's proposed Pitavastatin Calcium product is indicated as an adjunctive therapy to diet to reduce elevated total cholesterol (TC), low-density lipoprotein cholesterol (LDL-C), apolipoprotein B (Apo B), triglycerides (TG), and to increase HDL-C in adult patients with primary hyperlipidemia or mixed dyslipidemia. Sawai Pharma denies the remaining allegations in paragraph 30.

31. Sawai Pharma denies the allegations in Paragraph 31.

COUNT II
(INFRINGEMENT OF THE METHOD CLAIM OF THE '336 PATENT UNDER 35 U.S.C. §271(b)

32. Sawai Pharma restates and incorporates by references its answers to the allegations in Paragraphs 1-31.

33. Sawai Pharma denies the allegations in Paragraph 33.

34. Sawai Pharma avers that the proposed labeling for the ANDA product indicates that Sawai USA's proposed Pitavastatin Calcium product is indicated as an adjunctive therapy to diet to reduce elevated total cholesterol (TC), low-density lipoprotein cholesterol (LDL-C), apolipoprotein B (Apo B), triglycerides (TG), and to increase HDL-C in adult patients with primary hyperlipidemia or mixed dyslipidemia. Sawai Pharma denies the remaining allegations in paragraph 34.

35. Sawai Pharma denies the allegations in Paragraph 35.

36. Sawai Pharma denies the allegations in Paragraph 36.

COUNT III
(INFRINGEMENT OF THE METHOD CLAIM OF THE '336 PATENT UNDER 35 U.S.C. §271(c)

37. Sawai Pharma restates and incorporates by references its answers to the allegations in Paragraphs 1-36.

38. Sawai Pharma denies the allegations in Paragraph 38.

39. Sawai Pharma denies the allegations in Paragraph 39.

40. Sawai Pharma denies the allegations in Paragraph 40.

41. Sawai Pharma denies the allegations in Paragraph 41.

42. Sawai Pharma denies the allegations in Paragraph 42.

43. Sawai Pharma denies the allegations in Paragraph 43.

44. Sawai Pharma denies the allegations in Paragraph 44.

45. Sawai Pharma denies the allegations in Paragraph 45.

COUNT IV
(INFRINGEMENT OF THE '477 PATENT UNDER 35 U.S.C. §271(e)(2)(A)

46. Sawai Pharma restates and incorporates by references its answers to the allegations in Paragraphs 1-45.

47. Sawai Pharma admits that Sawai USA filed ANDA No. 205955 with the FDA seeking approval for Pitavastatin Calcium Tablets, 1 mg, 2 mg, and 4 mg prior to the expiration of, among others, the '477 patent. Sawai Pharma denies all remaining allegations in Paragraph 47.

48. Sawai Pharma admits that the letter dated June 6, 2014, referenced in paragraph 26 above states that the '477 patent is "invalid and/or the valid claims therein as not infringed, either literally or under the doctrine of equivalents, by the manufacture, use, sale, offer for sale, and/or importation of the drug or drug product for which the present ANDA has been submitted." Sawai Pharma denies the remaining allegations in paragraph 48.

49. Sawai Pharma denies the allegations in Paragraph 49.

50. Sawai Pharma denies the allegations in Paragraph 50.

51. Sawai Pharma denies the allegations in Paragraph 51.

COUNT V
(INFRINGEMENT OF THE '993 PATENT UNDER 35 U.S.C. §271(e)(2)(A)

52. Sawai Pharma restates and incorporates by references its answers to the allegations in Paragraphs 1-51.

53. Sawai Pharma avers that Sawai USA filed ANDA No. 205955 with the FDA seeking approval for Pitavastatin Calcium Tablets, 1 mg, 2 mg, and 4 mg prior to the expiration of, among others, the '993 patent. Sawai Pharma denies all remaining allegations in Paragraph 53.

54. Sawai Pharma admits that the letter dated June 6, 2014, referenced in paragraph 26 above states that the '993 patent "as invalid and/or the valid claims therein as not infringed, either literally or under the doctrine of equivalents, by the manufacture, use, sale, offer for sale, and/or importation of the drug or drug product for which the present ANDA has been submitted." Sawai Pharma denies the remaining allegations in paragraph 54.

55. Sawai Pharma denies the allegations in Paragraph 55.

56. Sawai Pharma denies the allegations in Paragraph 56.

57. Sawai Pharma denies the allegations in Paragraph 57.

Sawai Pharma denies all remaining allegations not specifically admitted herein. Sawai Pharma further denies that Plaintiffs are entitled to the relief requested, or to any relief whatsoever.

AFFIRMATIVE DEFENSES

Without prejudice to the denials set forth in this Answer, without admitting any allegations of the Complaint not otherwise admitted, and without undertaking any of the burdens imposed by law on the Plaintiffs, Sawai Pharma alleges and asserts the following defenses to the Complaint:

First Affirmative Defense

The product of ANDA No. 205955 does not infringe, and would not infringe any valid claim of the '336 patent if made, used, sold, offered for sale, marketed, or imported into the United States.

Second Affirmative Defense

The product of ANDA No. 205955 does not infringe, and would not infringe any valid claim of the '477 patent if made, used, sold, offered for sale, marketed, or imported into the United States.

Third Affirmative Defense

The product of ANDA No. 205955 does not infringe, and would not infringe any valid claim of the '993 patent if made, used, sold, offered for sale, marketed, or imported into the United States.

Fourth Affirmative Defense

The '336 patent and all its claims are invalid under 35 U.S.C. § 101 *et seq.*, including but not limited to 35 U.S.C. §§ 101, 102, 103, and/or 112.

Fifth Affirmative Defense

The '477 patent and all its claims are invalid under 35 U.S.C. § 101 *et seq.*, including but not limited to 35 U.S.C. §§ 101, 102, 103, and/or 112.

Sixth Affirmative Defense

The '993 patent and all its claims are invalid under 35 U.S.C. § 101 *et seq.*, including but not limited to 35 U.S.C. §§ 101, 102, 103, and/or 112.

Seventh Affirmative Defense

Plaintiffs are estopped from asserting any scope for one or more of the claims of the '336, '477 and '993 patents that would include the ANDA Products because of amendments, representations, assertions, disclaimers and/or admissions made during the course of proceedings in the United States Patent and Trademark Office ("PTO") during prosecution of the application leading to the issuance of the '336, '477 and '993 patents.

Eighth Affirmative Defense

To the extent not encompassed by Sawai Pharma's Seventh Defense, Plaintiffs are estopped from construing the claims of the '336, '477 and '993 patents to cover and include the ANDA Products.

Ninth Affirmative Defense

Any additional defenses or counterclaims that discovery may reveal, including enforceability.

COUNTERCLAIMS

Defendant/Counterclaimant Plaintiff Sawai Pharmaceutical Co., Ltd. ("Sawai Pharma" or "Counterclaim Plaintiff"), as and for its counterclaims against Kowa Company, Ltd., Kowa Pharmaceuticals America, Inc. (collectively "Kowa") and Nissan Chemical Industries, Ltd. ("NCI") (together "Plaintiffs" or "Counterclaim Defendants"), alleges as follows.

PARTIES

1. Sawai Pharmaceutical Co., Ltd. is a corporation organized under the laws of Japan, having its principal place of business at 5-2-30, Miyahara, Yodogawa-Ku, Osaka 532-0003, Japan.

2. Sawai USA, Inc. ("Sawai USA") is a partially owned subsidiary of Sawai Pharma (collectively referred to as "Sawai").

3. On information and belief, Kowa Pharmaceuticals America, Inc., is a corporation operating and existing under the laws of the State of Delaware, having its principal place of business at 530, Industrial Park Blvd., Montgomery, AL 36117.

4. On information and belief, Kowa Company, Ltd, is a Japanese corporation operating and existing under the laws Japan, having its principal place of business in Aichi, Japan.

5. On information and belief, Nissan Chemical Industries Ltd., is a Japanese corporation operating and existing under the laws Japan, having its principal place of business in Tokyo, Japan.

JURISDICTION AND VENUE

6. These counterclaims concerning U.S. Patent No. 5,856,336 ("the '336 patent") U.S. Patent No. 6,465,477 ("the '477 patent") and U.S. Patent No. 8,557,993 ("the '993 Patent") arise under the Patent Laws of the United States, 35 U.S.C. § 101 et seq., and the Declaratory Judgment Act, 28 U.S.C. §§ 2201 and 2202.

7. This Court has subject matter jurisdiction over these counterclaims pursuant to 28 U.S.C. §§ 1331, 1338(a), 1367(a), 2201 and 2202, and 35 U.S.C. § 1, *et seq.*

8. This Court has personal jurisdiction over Kowa and NCI because they have availed themselves of the rights and privileges of this forum by bringing this action in this district; and conduct substantial business in, and have regular and systematic contact with, this district.

9. Venue is proper in this District under 28 U.S.C. §§ 1391(b) and 1400 and because this suit was filed in this district by the Plaintiffs.

THE CONTROVERSY

10. This is an action based on an actual controversy between Counterclaim Plaintiff Sawai Pharma and Counterclaim Defendants Kowa and NCI concerning the invalidity and/or non-infringement of each of the '336, '477, and '993 patents-in-suit, and Sawai Pharma's right to continue to seek approval, through its partially owned subsidiary, Sawai USA, of Sawai USA's ANDA for the proposed Pitavastatin Calcium tablets, 1 mg, 2 mg, and 4 mg ("Proposed ANDA Product"), and upon approval by the FDA, to manufacture, use, sell and offer to sell and import into the United States the Proposed ANDA Product.

11. The '336 patent indicates on its face that it was issued by the USPTO on January 5, 1999, is entitled "Quinoline Type Mevalonolactones," and lists Nissan Chemical Industries Ltd., as assignee.

12. Plaintiffs allege that they purportedly own and have the right to enforce the '336 patent.

13. The '477 patent indicates on its face that it was issued by the USPTO on October 15, 2002, is entitled "Stable Pharmaceutical Composition," and lists Kowa Company, Ltd. and Nissan Chemical Industries, Ltd., as assignees.

14. Plaintiffs allege that they purportedly own and have the right to enforce the '477 patent.

15. The '993 patent indicates on its face that it was issued by the USPTO on October 15, 2013, is entitled "Crystalline Forms of Pitavastatin Calcium," and list Nissan Chemical Industries, Ltd. as assignee.

16. Plaintiffs allege that they purportedly own and have the right to enforce the '993 patent.

17. Plaintiffs submitted the '336, '477 and '993 patents to the United States Food and Drug Administration ("FDA") for listing in the FDA's publication, *Approved Drug Products with Therapeutic Equivalence Evaluations* (the "Orange Book"), in connection with approved New Drug Application No. 22-363 for LIVALO® (Pitavastatin Calcium) Tablets, 1 mg, 2 mg and 4 mg.

18. Plaintiffs have represented that one or more claims of the '336, '477, and '993 patents relate to its commercially marketed product LIVALO®, which contains the active

ingredient Pitavastatin calcium. Plaintiffs have alleged that one or more claims of the '336, '477, and '993 patents would be infringed by the ANDA Product, and that the filing of Sawai USA's ANDA constitutes infringement of the '336, '477, and '993 patents.

19. Sawai Pharma's partially owned subsidiary, Sawai USA, has submitted and is continuing to seek FDA approval of an ANDA directed to products containing Pitavastatin calcium, 1 mg, 2 mg, and 4 mg, and approval to engage in the commercial manufacture, use, offer for sale and importation into the United States, of its proposed products under that ANDA, before the expiration of the '336, '477, and '993 patents.

20. By letter dated June 6, 2014, Sawai USA notified Kowa and NCI that it had submitted to FDA ANDA No. 205955 directed to the Proposed ANDA Product, and stated that the manufacture, use, offer for sale, sale or importation of that Proposed ANDA Product would not infringe any valid claim of the '336, '477, and '993 patents.

21. On or about July 23, 2014, Plaintiffs sued Sawai Pharma and Sawai USA in this District alleging infringement of the '336, '477 and '993 patents under 35 U.S.C. §§ 271(e)(2)(A), 271(b), 271(c) and 281-83.

22. In view of the foregoing, an actual justiciable controversy exists by virtue of Sawai USA's notification to Kowa and NCI of its ANDA filing, and Kowa and NCIs' subsequent filing of the present suit.

COUNT I
(Declaratory Judgment of Non-Infringement of the '336 Patent)

23. Counterclaim Plaintiff Sawai Pharma repeats and incorporates the allegations of the foregoing paragraphs 1-22.

24. A justiciable case or controversy exists between Counterclaim Plaintiff Sawai Pharma, and Counterclaim Defendants Kowa and NCI, concerning the non-infringement of the '336 patent, which requires a declaration of rights by this Court.

25. Counterclaim Plaintiff Sawai Pharma has not manufactured, used, sold or offered for sale in the United States, or imported into the United States, any products that infringe any valid claims of the '336 patent, either literally or under the doctrine of equivalents.

26. Counterclaim Plaintiff Sawai Pharma has no adequate remedy at law and is entitled to a declaratory judgment that the commercial manufacture, use, offer for sale, or importation of the Proposed ANDA Product does not and will not infringe any valid claim of the '336 patent.

COUNT II
(Declaratory Judgment of Invalidity of the '336 Patent)

27. Counterclaim Plaintiff Sawai Pharma repeats and incorporates the allegations of the foregoing paragraphs 1-26.

28. A justiciable case or controversy exists between Counterclaim Plaintiff Sawai Pharma and Counterclaim Defendants Kowa and NCI which requires a declaration of rights by this Court.

29. The '336 patent is invalid for failure to meet the patentability requirements under 35 U.S.C. § 101 *et seq.*, including but not limited to 35 U.S.C. §§ 101, 102, 103 and/or 112.

30. Counterclaim Plaintiff Sawai Pharma has no adequate remedy at law and is entitled to a declaratory judgment that the '336 patent is invalid and/or void.

COUNT III
(Declaratory Judgment of Non-Infringement of the '477 Patent)

31. Counterclaim Plaintiff Sawai Pharma repeats and incorporates the allegations of the foregoing paragraphs 1-30.

32. A justiciable case or controversy exists between Counterclaim Plaintiff Sawai Pharma and Counterclaim Defendants Kowa and NCI concerning the non-infringement of the '477 patent, which requires a declaration of rights by this Court.

33. Counterclaim Plaintiff Sawai Pharma has not manufactured, used, sold or offered for sale in the United States, or imported into the United States, any products that infringe any valid claims of the '477 patent, either literally or under the doctrine of equivalents.

34. Counterclaim Plaintiff Sawai Pharma has no adequate remedy at law and is entitled to a declaratory judgment that the commercial manufacture, use, offer for sale, or importation of the Proposed ANDA Product does not and will not infringe any valid claim of the '477 patent.

COUNT IV
(Declaratory Judgment of Invalidity of the '477 Patent)

35. Counterclaim Plaintiff Sawai Pharma repeats and incorporates the allegations of the foregoing paragraphs 1-34.

36. A justiciable case or controversy exists between Counterclaim Plaintiff Sawai Pharma and Counterclaim Defendants Kowa and NCI which requires a declaration of rights by this Court.

37. The '477 patent is invalid for failure to meet the patentability requirements under 35 U.S.C. § 101 et seq., including but not limited to 35 U.S.C. §§ 101, 102, 103 and/or 112.

38. Counterclaim Plaintiff Sawai Pharma has no adequate remedy at law and is entitled to a declaratory judgment that the '477 patent is invalid and/or void.

COUNT V
(Declaratory Judgment of Non-Infringement of the '993 Patent)

39. Counterclaim Plaintiff Sawai Pharma repeats and incorporates the allegations of the foregoing paragraphs 1-38.

40. A justiciable case or controversy exists between Counterclaim Plaintiff Sawai Pharma and Counterclaim Defendants Kowa and NCI concerning the non-infringement of the '993 patent, which requires a declaration of rights by this Court.

41. Counterclaim Plaintiff Sawai Pharma has not manufactured, used, sold or offered for sale in the United States, or imported into the United States, any products that infringe any valid claims of the '993 patent, either literally or under the doctrine of equivalents.

42. Counterclaim Plaintiff Sawai Pharma has no adequate remedy at law and is entitled to a declaratory judgment that the commercial manufacture, use, offer for sale, or importation of the Proposed ANDA Product does not and will not infringe any valid claim of the '993 patent.

COUNT VI
(Declaratory Judgment of Invalidity of the '993 Patent)

43. Counterclaim Plaintiff Sawai Pharma repeats and incorporates the allegations of the foregoing paragraphs 1-42.

44. A justiciable case or controversy exists between Counterclaim Plaintiff Sawai Pharma and Counterclaim Defendants Kowa and NCI which requires a declaration of rights by this Court.

45. The '993 patent is invalid for failure to meet the patentability requirements under 35 U.S.C. § 101 et seq., including but not limited to 35 U.S.C. §§ 101, 102, 103 and/or 112.

46. Counterclaim Plaintiff Sawai Pharma has no adequate remedy at law and is entitled to a declaratory judgment that the '993 patent is invalid and/or void.

PRAYER FOR RELIEF

WHEREFORE, Defendant/Counterclaim Plaintiff Sawai Pharmaceutical Co., Ltd. prays that the Court enter judgment in its favor and against Plaintiff/Counterclaim Defendants Kowa Company Ltd., Kowa Pharmaceuticals America, Inc., and Nissan Chemical Industries, Ltd.:

a. Declaring that the manufacture, use, offer for sale, sale, or importation of the proposed products that are the subject of ANDA No. 205955 has not infringed, does not infringe, and would not, if marketed, infringe any valid and enforceable claim of the '336 patent;

b. Declaring that the claims of the '336 patent are invalid;

c. Declaring that the manufacture, use, offer for sale, sale, or importation of the proposed products that are the subject of ANDA No. 205955 has not infringed, does not infringe, and would not, if marketed, infringe any valid and enforceable claim of the '477 patent;

d. Declaring that the claims of the '477 patent are invalid;

e. Declaring that the manufacture, use, offer for sale, sale, or importation of the proposed products that are the subject of ANDA No. 205955 has not infringed, does not infringe, and would not, if marketed, infringe any valid and enforceable claim of the '993 patent;

f. Declaring that the claims of the '993 patent are invalid;

g. Declaring that Sawai Pharma, through its partially owned subsidiary, Sawai USA, Inc. has a lawful right to seek and obtain FDA approval of Sawai USA's ANDA for the Proposed ANDA Product and that based on the noninfringement, invalidity and/or unenforceability of the '336, '477 and '993 patents, Sawai has a right to import, manufacture, use, offer for sale and sell the Proposed ANDA Product once approved by the FDA;

h. Ordering that Kowa and NCI, its officers, agents, servants, employees and attorneys, and those persons in active concert or participation with them, be preliminarily and permanently enjoined from threatening or initiating further infringement litigation against Sawai or any of its customers, dealers or suppliers, or any prospective sellers, dealers, distributors or customers of Sawai or charging any of them either orally or in writing with infringement of the '336, '477 and '993 patents;

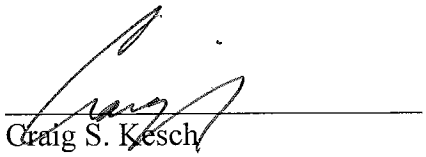
i. Ordering that Plaintiffs' Complaint be dismissed with prejudice and judgment entered in favor of Defendant/Counterclaim Plaintiff;

j. Declaring this an exceptional case in favor of Sawai Pharma and awarding attorneys' fees, costs and expenses pursuant to 35 U.S.C. § 285;

k. Awarding any and all such other relief as the Court determines to be just and proper.

Dated: New York, New York
March 19, 2015

FLEMMING ZULACK
WILLIAMSON ZAUDERER LLP



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